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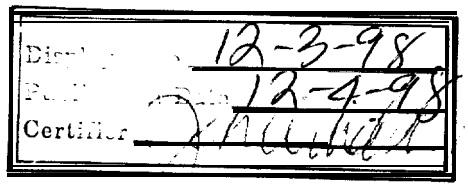

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98P-0425]

Medical Devices; Exemptions From Premarket Notification; Surgical Lamps

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice,

SUMMARY: The Food and Drug Administration (FDA) is publishing an order denying a petition requesting an exemption from the premarket notification requirements for surgical lamps. FDA is publishing this notice in accordance with procedures established by the Food and Drug Administration Modernization Act of 1997 (FDAMA).

EFFECTIVE DATE: (*Insert date of publication in the* **Federal Register.)**

FOR FURTHER INFORMATION CONTACT: Heather S. Rosecrans, Center for Devices and Radiological Health (HFZ–404), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-1190.

SUPPLEMENTARY INFORMATION:

I. Statutory Background

Under section 513 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c), FDA must classify devices into one of three regulatory classes: Class I, class II, or class HI. FDA classification of a device is determined by the amount of regulation necessary to provide a reasonable assurance of safety and effectiveness. Under the Medical Device Amendments of 1976 (the 1976 amendments (Pub. L. 94-295)), as amended by the Safe Medical Devices Act of 1990 (the SMDA (Pub. L. 101-629)), devices are to be classified into class I (general controls) if there is information showing that the general controls of the act are sufficient to assure safety and

effectiveness; into class II (special controls), if general controls, by themselves, are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide such assurance; and into class III (premarket approval), if there is insufficient information to support classifying a device into class I or class 11 and the device is a life-sustaining or life-supporting device or is for a use which is of substantial importance in preventing impairment of human health, or presents a potential unreasonable risk of illness or injury.

Most generic types of devices that were on the market before the date of the 1976 amendments (May 28, 1976) (generally referred to as preamendments devices) have been classified by FDA under the procedures set forth in section 5 13(c) and (d) of the act through the issuance of classification regulations into one of these three regulatory classes. Devices introduced into interstate commerce for the first time on or after May 28, 1976 (generally referred to as postamendments devices) are classified through the premarket notification process under section 510(k) of the act (21U.S.C.360(k)). Section 510(k) of the act and the implementing regulations, 21 CFR part 807, require persons who intend to market a new device to submit a premarket notification report (5 10(k)) containing information that allows FDA to determine whether the new device is ' 'substantially equivalent" within the meaning of section 513(i) of the act to a legally marketed device that does not require premarket approval.

On November 21, 1997, the President signed into law FDAMA (Pub. L. 105–1 15). Section 206 of FDAMA, in part, added a new section 5 10(m) to the act. Section 5 10(m)(1) of the act requires FDA, within 60 days after enactment of FDAMA, to publish in the **Federal Register** a list of each type of class 11 device that does not require a report under section 5 10(k) of the act to provide reasonable assurance of safety and effectiveness. Section 510(m) of the act further provides that a 5 10(k) will no longer be required for these devices upon the date of publication of the list in the **Federal Register.** FDA published that list in the **Federal Register** of January 21, 1998 (63 FR 3142).

Section 510(m)(2) of the act provides that, 1 day after date of publication of the list under section 510(m)(1), FDA may exempt a device on its own initiative or upon petition of an interested person, if FDA determines that a 5 10(k) is not necessary to provide reasonable assurance of the safety and effectiveness of the device. This section requires FDA to publish in the **Federal Register** a notice of intent to exempt a device, or of the petition, and to provide a 30-day comment period. Within 120 days of publication of this document, FDA must publish in the **Federal Register** its final determination regarding the exemption of the device that was the subject of the notice. If FDA fails to respond to a petition under this section within 180 days of receiving it, the petition shall be deemed granted.

II. Criteria for Exemption

There are a number of factors FDA may consider to determine whether a 510(k) is necessary to provide reasonable assurance of the safety and effectiveness of a elms II device. These factors are discussed in the guidance the agency issued on February 19, 1998, entitled "Procedures for Class II Device Exemptions from Premarket Notification, Guidance for Industry and CDRH Staff. " That guidance can be obtained through the World Wide Web on the CDRH home page at "http://www.fda.gov/cdrh`` or by facsimile through CDRH Facts-on-Demand at 1-800–899-0381 or 301-827-0111. Specify `` 159" when prompted for the document shelf number.

III. Petitions

On June 17, 1998, FDA received a petition requesting an exemption from premarket notification for surgical lamps from Getinge/Castle, Inc. On September 30, 1998 (63 FR 52275), FDA published a notice announcing that it had received three petitions, including the one from Getinge/Castle, Inc., requesting exemption from premarket notification for class II devices and providing an opportunity for interested persons to submit comments on the petitions by October 30, 1998. FDA received no comments. FDA has reviewed these petitions and, for the following reasons, has determined that surgical lamps do not meet the criteria for exemption described

previously and is, therefore, issuing this order denying the petition to exempt these devices from the requirements of premarket notification The other two peti[ions will be addressed separately in another issue of the **Federal Register.**

FDA has determined from its medical devices reporting (MDR) database that there is a risk of over-exposure to ultraviolet (UV) light from surgical lamps and there is a risk of surgical lamps falling on surgical personnel during use. FDA has recently completed a guidance document for surgical lamps entitled ' 'Guidance Document for Surgical Lamp 510(k)s.'' FDA is also aware of a draft standard from the International Electrotechnical Commission (IEC), IEC–6060 1–2-41, that would be applicable. FDA believes that the guidance and the draft standard would address the risks to health presented by surgical lamps. At some time in the future. FDA may adopt the

guidance document and the IEC standard as special controls for surgical lamps. Without the guidance and the IEC standard as special controls. FDA believes that premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of sunlamps.

Dated: 11-23-98

November 23, 1998

D.B. Burlington
Director
Center for Devices and Radiological Health

[FR Dec. 98-'?'?'?'? Filed '? '?-'? '?-98; 8:45am]

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